

39. (Once amended) A purified polypeptide comprising an amino acid sequence selected from the group consisting of:

[c)] a) an amino acid sequence of SEQ ID NO:2,

[d)] b) [a naturally-occurring] an amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2, wherein amino acid sequence is a member of the sca-2 family polypeptides.

[e)] c) a biologically-active fragment of the amino acid sequence of SEQ ID NO:2, wherein said biologically-active fragment is a member of the sca-2 family polypeptides, and

[f)] d) an immunogenic fragment of the amino acid sequence of SEQ ID NO:2, wherein said immunogenic fragment is capable of generating an antibody that specifically binds to the polypeptide encoded by SEQ ID NO:2.

REMARKS

Claims 13, 17, and 19-39 are pending in this divisional application. Claim 18 was canceled in the previous response to the restriction requirement filed April 12, 2000. Claims 13, 17, and 19-38 have been withdrawn from consideration as being directed to a non-elected invention. Applicants reserve the right to prosecute the canceled and withdrawn claims in subsequent applications. Claim 39 is the solely remaining claim being examined. Claim 39 has been amended to further clarify the invention. Support for the amendment can be found in the specification, on page 1, lines 10-34, and page 6, lines 5-14, where Applicants discuss the functions and characteristics of sca-2, on page 18, lines 8-17, where Applicants discuss the use of the claimed polypeptides, and on page 38, lines 4-12, where Applicants discuss the activities of the claimed polypeptides. No new matter is added by these amendments. Entry of these amendments is respectfully requested. Applicants thank the Examiner's recognition that the method claims depending upon the allowable claims will be rejoined at the time the produce claims are found allowable.

Information Disclosure Statement

Initially, it is noted that the Examiner failed to completely examine Applicants' invention. Specifically, Applicants object to the Examiner's failure to obtain the parent application and

references therein prior to preparing this Office Action. Therefore, Applicants insist that the Examiner do so, that she fully consider the references cited in the parent application and listed on the Form 1449. In no case should any rejection in a subsequent Office Action relating to the Examiner's failure to obtain the parent file be made final.

Rejection under 35 U.S.C. 112, second paragraph for indefiniteness

Claim 39 stands rejected under 35 U.S.C. 112, second paragraph as being allegedly indefinite. The Examiner objected to the use of the term "naturally-occurring". As amended herein, claim 39 does not recite the term "naturally-occurring". The Examiner also objected to the use of "biologically active fragment", alleging that it is unclear what that term means. As amended herein, the term "biologically active fragment" is specifically limited to the functional language that defines the term. Thus, the Examiner's concerns have been addressed with respect to the claim language by entry of these amendments. Withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. 112, first paragraph for lack of enablement

Claim 39 is rejected under 35 U.S.C. 112, first paragraph for allegedly not enabled. The Examiner alleged that there is no instruction in the specification for using all sequences having 90% homology to SEQ ID NO:2, and that no further guidance or working examples were disclosed in the specification for relating sequences changes to functional activities. Applicants respectfully traverse.

Claim 39 as amended recite a purified polypeptide comprising an amino acid sequence selected from the group consisting of an amino acid sequence of SEQ ID NO:2, an amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2, wherein amino acid sequence is a member of the sca-2 family polypeptides, a biologically-active fragment of the amino acid sequence of SEQ ID NO:2, wherein said biologically-active fragment is a member of the sca-2 family polypeptides, and an immunogenic fragment of the amino acid sequence of SEQ ID NO:2, wherein said immunogenic fragment is capable of generating an antibody that specifically binds to the polypeptide encoded by SEQ ID NO:2. Thus, it can be seen that there are specific definitions of the types of fragment polypeptides that are within the scope of the invention being claimed herein.

Applicants believe that there should be no problem with such "90%" language, since, given the current state of computing technology, it would be easy and routine for one of skill in the art to determine if he/she has a DNA sequence that is 90% identical to that of SEQ ID NO:1, and further, it would be a routine matter to supply a list of all possible proteins that are at least 90% identical to that of SEQ ID NO:1. Having produced a sequence with at least 90% identity to SEQ ID NO 1, it would again be a routine matter, without undue experimentation, to use the assay as set out on page 38 of the specification to determine if the protein had the specified biological activity (as an sca-2 protein). Additionally, applicants would like to point out that the specification does point out the important conserved structural elements of the protein at page 6, which would make it even easier for one of skill to determine the likely activity of a variant polypeptide. Thus this rejection is moot to the amended claims, and applicants respectfully request that it be repealed.

Rejection under 35 U.S.C. 112, first paragraph for lack of written description

Claim 39 also stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not sufficiently described to indicate that the Applicants had the possession of the claimed invention. Essentially, the Examiner argued that the specification only disclosed SEQ ID NO:2, and that the claim language encompasses a lot more types of polypeptides. Applicants disagree with the Examiner's assertions, and respectfully traverse.

Again, claim 39 as amended specifically defines the types of fragments that are within the scope of the claimed invention. There are ample teachings in the specification regarding how to make and use the claimed fragments, as discussed above. Thus, the Examiner has not provided sound reasoning or solid evidence on why one with ordinary skill in the art would question that Applicants had the possession of the claimed invention at the time the application was filed. In fact, the teachings and the general level of skills in the art would more likely than not convince the skilled artisan that Applicants indeed possessed the claimed invention as in amended claim 39. Therefore, the Examiner is respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. 102

Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by any of Wilkie et al, or Wray et al, or Burton et al, or Gama et al, or Birkland, or Arendt et al. The Examiner alleged

that the cited references disclosed a fragment of SEQ ID NO:2 which can generate an immune response to the host.

It is well settled in patent law that a reference is anticipating under 35 U.S.C. § 102 (b) only if **all** elements of the claimed invention are disclosed in the reference. *In re Paulsen*, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994). In the instant case, the relevant claim language in claim 39 reads: an immunogenic fragment of the amino acid sequence of SEQ ID NO:2, wherein said immunogenic fragment is capable of generating an antibody that specifically binds to the polypeptide encoded by SEQ ID NO:2. None of the references cited by the Examiner disclosed a fragment which is capable of generating an antibody that "specifically" binds to SEQ ID NO:2. Thus, not all limitations of claim 39 are found in the cited references. The Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. 102.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (650)855-0555.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108. **This form is enclosed in duplicate.**

Respectfully submitted,
INCYTE GENOMICS, INC.

Date: _____

10/15/00



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